

Appl. No. 09/774,556
Atty. Docket No. 7999
Amdt. dated 11/13/2003
Reply to Office Action of 05/14/2003
Customer No. 27752

REMARKS

Claims 1-51 are pending in the present application. Claims 11, 12, 16, 21-25, 35, 36, 40, 47 and 50 have been withdrawn from further consideration, as being drawn toward non-elected subject matter. Claims 1, 3, 20-25 and 44 have been amended to particularly point out and distinctly claim the subject matter that the Applicants regard as their invention.. Support for the present Amendments is found throughout the specification and claims as originally filed. No new matter has been added and no additional claims fees are believed to be due. The Applicants strongly believe that the present Amendments and accompanying Remarks have placed the present application in condition for allowance. Accordingly, timely and favorable action is respectfully requested.

Election/Restriction Under 35 USC 121

The Office Action asserts that restriction to one of the following inventions is required under 35 USC 121:

- I. Claims 1-49, 51, drawn to a composition comprising an active ingredient consisting of oximyl and hydroxylamino prostaglandins having the functionality as recited in claim 1 and a carrier, classified in class 514, subclass 573.

- II. Claim 50, drawn to a mascara composition comprising an active ingredient consisting of oximyl and hydroxylamino prostaglandins having the functionality as recited in claim 50, a water insoluble material, a water-soluble film forming polymer, a wax, a surfactant, a pigment, and a solvent, classified in class 424, subclass 70.7.

The Applicants hereby affirm their telephonic election to prosecute the subject matter of Group I, without traverse. The Applicants hereby further affirm their telephonic election to prosecute the species of 11-oximyl-15-methyl-17-(2-fluorophenyl)-17-trinor-PGD2 methyl ester, wherein water is the carrier and wherein minoxidil is the activity enhancer.

Rejection Under 35 USC 112, Second Paragraph

The Office Action asserts that claims 1, 3, 20, 26-27, 44 and 51 are rejected under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicants regard as their invention. Specifically, the Office Action asserts that the phrases "a heterogeneous group" and a "substituted heterogeneous group" in claims 1, 3, 26, 27 and 51 are vague and indefinite as the meaning of said phrases is purportedly

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unclear as to which chemical constituents are encompassed by the phrases. The Office Action further asserts that claims 20 and 44 are rejected for the use of improper Markush groups.

Regarding inclusion of the phrases "heterogeneous group" and "substituted heterogeneous group" in claims 1, 3, 26, 27 and 51, the Applicants respectfully submit that said phrases are clearly defined in the present specification, and thus, are neither vague nor indefinite. In this respect, the Applicants respectfully direct the Examiner's attention to page 8 of the present specification, in which the Applicants clearly define,

"Heterogeneous group" means a saturated or unsaturated chain containing 1 to 18 member atoms (i.e., including both carbon and at least one heteroatom). No two heteroatoms are adjacent. Preferably, the chain contains 1 to 12 member atoms, more preferably 1 to 6, most preferably 1 to 4. The chain may be straight or branched. Preferred branched heterogeneous groups have one or two branches, preferably one branch. Preferred heterogeneous groups are saturated. Unsaturated heterogeneous groups have one or more double bonds, one or more triple bonds, or both. Preferred unsaturated heterogeneous groups have one or two double bonds or one triple bond. More preferably, the unsaturated heterogeneous group has one double bond. Heterogeneous groups are unsubstituted (emphasis added).

The Applicants further wish to direct the Examiner's attention to page 10 of the present specification, in which the Applicants clearly indicate,

"Substituted heterogeneous group" means a heterogeneous group, wherein at least 1 of the hydrogen atoms bonded to a carbon atom in the chain has been replaced with another substituent. Preferred substituents include halogen atoms, hydroxy groups, alkoxy groups (e.g., methoxy, ethoxy, propoxy, butoxy, and pentoxy), aryloxy groups (e.g., alkylloxycarbonylphenoxy, acyloxyphenoxy), acyloxy groups (e.g., propionyloxy, benzyloxy, and acetoxy), carbamoyloxy groups, carboxy groups, mercapto groups, alkythio groups, acylthio groups, arylthio groups (e.g., phenylthio, chlorophenylthio, alkylphenylthio, alkoxyphenylthio, benzylthio, and alkylloxycarbonylphenylthio), aromatic groups (e.g., phenyl and tolyl), substituted aromatic groups (e.g., alkoxyphenyl, alkoxy carbonylphenyl, and halophenyl), heterocyclic groups, heteroaromatic groups, and amino groups (e.g., amino, mono- and di- alkylamino having 1 to 3 carbon atoms, methylphenylamino, methylbenzylamino, alkanyl amido groups of 1 to 3 carbon atoms, carbamamido, ureido, and guanidine).

In light of the above disclosure, the Applicants respectfully submit, and strongly urge, that a person of ordinary skill in the art would readily be apprised of the meaning of the phrases "heterogeneous group" and "substituted heterogeneous group." The Applicants further submit that the meaning and scope of said phrases is neither vague nor indefinite. Accordingly, the Applicants respectfully request reconsideration and withdrawal of the rejection to claims 1, 3, 26, 27 and 51 under 35 USC § 112, second paragraph.

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Regarding the use of purportedly improper Markush groups in claims 20 and 44, the Applicants wish to direct the Examiner's attention to the "Amendments" section of the instant paper, in which the Applicants have amended claims 20-25 and 44 to particularly point out and distinctly claim the subject matter that the Applicants regard as their invention. Support for the present amendments is found throughout the specification and claims as originally filed. Specifically, the Applicants have amended claims 20-25 and 44 to clarify the groups from which each ingredient defined therein are selected. In light of the present amendments, the Applicants respectfully request reconsideration and withdrawal of the rejection to claims 20 and 44 under 35 USC 112, second paragraph.

Rejection Under 35 USC 102 Over deLong

The Office Action asserts that claims 1-10, 13-15, 17 and 20 are rejected under 35 USC 102(a) as being unpatentable over WO 99/50241 to deLong (hereinafter "deLong"). Specifically, the Office Action asserts that deLong teaches C₁₁ oxymyl and hydroxylamino prostaglandins useful as medicants, including the purported exemplification of a composition comprising 11-oxymyl-13,14-dihydro-17-(2-fluorophenyl) 17 trinor PGD, water, dextran 70, hydroxylpropyl methylcellulose, sodium chloride, potassium chloride, disodium EDTA, benzalkonium chloride, and HCl and/or NaOH. The Office Action further states that both deLong and the instant invention teach compositions comprising a carrier (water) and oximyl and hydroxylamino prostaglandins having the functionality of the structure recited in claim 1, wherein C is bonded with a cyclopentyl ring, R₂ and R₃ form a covalent bond, and R₄ is H, and the structure recited in claim 3, wherein R₂ and R₃ form a covalent bond, R₄ is H, a is a single bond, c is a single bond, W is (CH₂)₂, R₁ is CO₂H, R₅ and R₆ are H, X is OH, Y is a direct bond, p is 2, q is 0 and Z is a substituted aromatic group.

The Applicants wish to direct the Examiner's attention to the "Amendment" section of the instant paper, in which the Applicants have amended claims 1 and 3, from which the balance of the above-identified claims ultimately depend, to particularly point out and distinctly claim the subject matter that Applicants regard as their invention. Support for the present amendments is found throughout the specification and claims, as originally filed. In light of the present amendments, the Applicants respectfully submit that the above-identified claims, as amended, no longer encompass a composition comprising 11-oxymyl-13,14-dihydro-17-(2-fluorophenyl) 17 trinor PGD, water, dextran 70, hydroxylpropyl methylcellulose, sodium chloride, potassium chloride, disodium EDTA, benzalkonium chloride, and HCl and/or NaOH, and thus, cannot be anticipated by the disclosure of deLong. Accordingly, the Applicants respectfully request reconsideration and withdrawal of the rejection to claims 1-10, 13-15, 17 and 20 under 35 USC 102(a).

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Rejection Under 35 USC 103(a) Over deLong

Claims 18, 26-34, 37-39, 41-44 and 48-49 have been rejected under 35 USC 103(a) as being unpatentable over deLong. The Office Action asserts that the deLong reference exemplifies 11-oximyl-15-ethyl-18-phenyl-18-dinor-PGD₂, which purportedly reads upon the instant claims when W is (CH₂)₂, R₁ is CO₂H, X is OH, Y is a bond, Z is an aromatic group, R₅ is C₂H₅ and H, R₆ is OH and H, p is 3, q is 0, a is a double bond, c is a single bond, and b is a double bond. The Office Action asserts that it would have been obvious to a person of ordinary skill in the art at the time the invention was made to exemplify the composition of deLong as being administered to a mammal.

The Applicants respectfully traverse the above-described rejection over deLong. The Applicants wish to note and underscore to the Examiner that present claims 18, 26-34, 37-39, 41-44 and 48-49 all relate to methods of treating hair loss in a mammal. The Applicants further submit that the hairless condition to which the claims of the present application are directed, is neither taught nor suggested by any indication disclosed in the deLong reference. Indeed, the Examiner acknowledges that deLong only exemplifies use of the subject compositions for treating the following indications: ocular disorders, hypertension, fertility control, nasal congestion, neurogenic bladder disorder, gastrointestinal disorders, dermatological disorders and osteoporosis. In this respect, the Applicants submit that the ordinary meaning of dermatological disorders does not encompass the hairless condition to which the claims of the present application are directed. Moreover, unlike deLong, the compositions and methods of the present invention are not administered systemically. Rather, the compositions and methods of the present invention are administered locally and, in fact, are adapted to minimize systemic absorption. Thus, the Applicants submit that it would not have been obvious to a person of ordinary skill in the art, at the time the invention was made, to exemplify the composition of deLong as being administered to a mammal for the treatment of hair loss. The Office Action has failed to establish a *prima facie* case of to the contrary. Accordingly, the Applicants respectfully request reconsideration and withdrawal of the rejection to claims 18, 26-34, 37-39, 41-44 and 48-49 under 35 USC 103(a) as being unpatentable over deLong.

Rejection Under 35 USC 103(a) Over deLong in view of Nathanson

Claims 19, 45, 46 have been rejected under 35 USC 103(a) as being unpatentable over deLong in view of US Patent Number 5,500,230 to Nathanson (hereinafter "Nathanson"). The Office Action asserts that Nathanson teaches a method for the treatment of glaucoma with nitrogen-containing guanylate cyclease activators. The Office Action further states that Nathanson exemplifies a method of treating glaucoma in an individual comprising systemically administering a therapeutically effective amount of minoxidil. The Office Action asserts that it

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would have been obvious to a person of ordinary skill in the art at the time the invention was made to add the minoxidil of Nathanson to the composition of deLong because both Nathanson and deLong are directed toward treating glaucoma and it is obvious to combine two compositions taught by the prior art to be useful for the same purpose to form a third composition that is to be used for the very same purpose, citing *In re Kerosene*, 205 SUP 1069 (COCA 1980).

The Applicants respectfully traverse the above-described invention. The Applicants wish to note that the Examiner's citation of *In re Kerkoven* is not dispositive for purposes of the present rejection. *In re Kerkoven*, as the Examiner correctly notes, held that it is obvious to combine two compositions taught by the prior art to be useful for the same purpose to form a third composition that is used for the very same purpose. The Applicants submit that, indeed, the subject compositions of deLong and Nathanson are both disclosed to be useful in the treatment of glaucoma (*i.e.*, useful for the same purpose). However, the claims of the present application are not directed to the treatment of glaucoma. Rather, the claims of the present application are expressly directed to the treatment of hair, and specifically hair loss in mammals. The Applicants further submit that deLong in view of Nathanson neither teach nor suggest use of the compositions and methods disclosed therein for the treatment of hair or hair loss. Thus, the Applicants submit that, although the compositions of deLong and Nathanson are useful for the same purpose, it would not have been obvious to a person of ordinary skill in the art to combine said compositions to be used for a materially-different purpose. Accordingly, the Applicants respectfully request reconsideration and withdrawal of the rejection to claims 19, 45 and 46 over 35 USC 103(a) as being unpatentable over deLong in view of Nathanson.

Rejection Under 35 USC 103(a) Over deLong in view of Johnstone

Claim 51 has been rejected under 35 USC 103(a) as being unpatentable over deLong in view of US Patent Number 6,262,105 to Johnstone et al (hereinafter "Johnstone"). The Office Action states that Johnstone teaches a method of enhancing hair growth comprising topically applying a composition comprising prostaglandins to the scalp and hair, and further discloses that prostaglandins useful in glaucoma treatment are useful in enhancing hair growth. The Office Action further states that it would have been obvious to one of ordinary skill in the art at the time the invention was made to disclose the use of the composition taught by deLong as being applied to hair growth, as disclosed by Johnstone because (a) deLong teaches compositions comprising prostaglandins for use in the treatment of dermatological disorders and (b) Johnstone teaches that prostaglandins, such as those used in the treatment of glaucoma are also useful in the enhancement of hair growth.

The Applicants respectfully traverse the above-described rejection. The Applicants respectfully submit that Johnstone teaches numerous classes of prostaglandins useful in the

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treatment of glaucoma. Indeed, Johnstone further discloses that prostaglandins, such as those useful in the treatment of glaucoma, are also useful in the enhancement of hair growth. The Examiner correctly notes that the prostaglandins of deLong are disclosed as being useful in the treatment of glaucoma. Nevertheless, the Applicants submit that, following extensive analysis and testing, the Applicants have learned (and documented via the present application) that, contrary to the disclosure of Johnstone, only a single group of prostaglandins, namely the Prostaglandin F group to which the present application lays claim, demonstrate meaningful activity in the treatment of mammalian hair conditions. The Applicants further submit that Johnstone provides no guidance to a person of ordinary skill in the art as to which of the numerous prostaglandin groups disclosed therein as being useful in the treatment of glaucoma, are also useful in the treatment of mammalian hair conditions. The Applicants submit that, in light of the few number of prostaglandins actually useful in the treatment of mammalian hair (and hairless) conditions, the disclosure of Johnstone would clearly require a person of ordinary skill in the art to engage in undue experimentation to arrive at the conclusion that only the Prostaglandin F group is useful for such treatment. Thus, it would not have been obvious to a person of ordinary skill in the art at the time the invention was made to use the composition of deLong in the treatment of mammalian hair growth. The Office Action fails to establish a *prima facie* case to the contrary. Accordingly, the Applicants respectfully request reconsideration and withdrawal of the rejection to claim 51 under 35 USC 103(a) over deLong in view of Johnstone.

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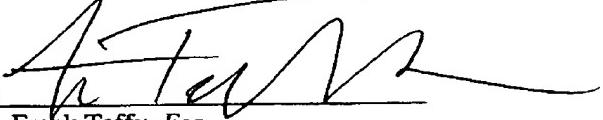
CONCLUSION

Applicants have made an earnest effort to place their application in proper form and to distinguish the invention as now claimed from the applied references. In view of the foregoing, Applicants respectfully request reconsideration of this application, entry of the amendments presented herein, and allowance of Claims 1-10, 13-15, 17-20, 26-34, 37-39, 41-46, 48-49 and 51, as amended. Should issues remain prior to allowance of the present case, then the Examiner is invited to contact the Applicants' legal representative.

Respectfully submitted,

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